Complete Summary

GUIDELINE TITLE

APIC guideline for infection prevention and control in flexible endoscopy.

BIBLIOGRAPHIC SOURCE(S)

Association for Professionals in Infection Control and Epidemiology, Inc. APIC guideline for infection prevention and control in flexible endoscopy. Am J Infect Control 2000;28:138-55. [96 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Nosocomial infection

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Gastroenterology
Infectious Diseases
Internal Medicine
Preventive Medicine

INTENDED USERS

Allied Health Personnel
Hospitals
Physicians

GUIDELINE OBJECTIVE(S)

To update the 1994 guideline on infection prevention and control in flexible endoscopy (Martin MA, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. AJIC Am J Infect Control 1994;2:19-38.)

TARGET POPULATION

Health care personnel and specifically, endoscopy unit personnel

INTERVENTIONS AND PRACTICES CONSIDERED

1. Processing of endoscopes and accessories, including:
    A. Manual cleaning of flexible endoscopes
    B. Automated endoscopic reprocessing
    C. Sterilization and disinfection procedures, including:
        - Agents recommended for high level disinfection of flexible endoscopes (e.g., glutaraldehyde preparations, hydrogen peroxide, peracetic acid, peracetic acid and hydrogen peroxide, and orthophalaldehyde)
        - Agents not recommended for disinfection of flexible endoscopes (e.g., products not cleared by the Food and Drug Administration [FDA], skin antiseptics, hypochlorite, quaternary ammonium compounds, phenolics)
        - New technologies for which there are insufficient data regarding sterilization/disinfection of endoscopes (e.g., chlorine dioxide, ozone, vapor-phase hydrogen peroxide, plasma technology, super oxidized water, and disposable, sterile-sheathed flexible endoscopes)
    D. Treatment of the endoscope after disinfection or sterilization, including rinsing, drying and storage
2. Reuse of single-use endoscopy devices/accessories (see Qualifying Statements field)
3. Quality control assessment of the adequacy of disinfection/sterilization

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Recent attention has been focused on the possibility that "single-use" devices could be reprocessed and reused both safely and cost effectively. Such savings can be considerable, but studies to date have included only a few such devices. As a result, this approach remains controversial, and implementation of such a strategy requires a major institutional commitment, including a monitoring committee with clearly defined protocols. Manufacturers need to improve the design of endoscope accessories to ensure the ability to be safely and effectively cleaned and sterilized.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

These guidelines represent minimum standards of care. Facilities may wish to adopt more stringent criteria. These recommendations should be followed for all patients, regardless of whether they are suspected or known to be infected.

1. Meticulous cleaning of the endoscope with an enzymatic detergent recommended by the endoscope manufacturer should be performed immediately after use. All of the channels should be irrigated and brushed, if accessible, to remove particulate matter. Irrigation adapters should be used to facilitate cleaning of all channels. All immersible parts of the endoscope should then be rinsed with water. Detergent solutions should be discarded after each use. Cleaning brushes should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use.
2. Leak testing is recommended for flexible endoscopes before immersion.
3. Endoscopes that pass through normally sterile tissue should be subjected to a sterilization procedure before each use; if this is not feasible, they should receive at least high-level disinfection. Disinfection should be followed by a rinse with sterile water.
4. Endoscopes that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection.
5. A Food and Drug Administration (FDA)-cleared sterilant/disinfectant should be used for sterilization or high-level disinfection.
6. Products and methods for cleaning and disinfection/sterilization should be compatible with the endoscopic equipment and design. Contact instrument manufacturer(s) to confirm compatibility.
7. If glutaraldehyde is used, all immersible internal and external surfaces should be in contact with the disinfectant for not less than 20 minutes to achieve high-level disinfection.
8. Personnel assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and disinfection or sterilization.
9. Nonimmersible endoscopes should be phased out immediately.
10. After chemical disinfection, endoscopes must be rinsed with sterile water or with tap water followed by 70% ethyl or isopropyl alcohol rinse.
11. The instrument and its channels should be thoroughly air-dried. A final drying step that includes flushing all channels with alcohol followed by purging the channels with air greatly reduces the possibility of recontamination of the endoscope by waterborne microorganisms.
12. Endoscopes should be stored in a manner that will protect the endoscope and minimize the potential for accumulation of residual moisture. They should not be coiled or stored in cases that cannot be properly cleaned. Endoscopes should be hung in a vertical position to facilitate drying.
13. Reusable accessories that penetrate mucosal barriers (e.g., biopsy forceps, cytology brushes) should be mechanically cleaned (i.e., by ultrasonics) and then steam sterilized between each patient or used once and discarded.
14. Sterile water should be used to fill the water bottle. The water bottle and its connecting tube should be sterilized or receive high-level disinfection at least daily.
15. Flexible endoscopes that cannot withstand the processes described in these guidelines because of age, design, or damage should not be used.
16. A log should be maintained indicating for each procedure the patient's name and medical record number, the procedure, the endoscopist, and the serial number or other identifier of the endoscope used.

17. In the setting of an outbreak caused by a suspected infections or chemical etiology, the investigation should be performed according to standard methods of outbreak investigations.
18. Endoscopy related infection or pseudoinfection should be reported to: (1) persons responsible for institutional infection control and risk management, (2) FDA, (3) state health department, (4) Centers for Disease Control and Prevention (CDC), and (5) manufacturer(s).
19. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for healthcare workers as well as patients. Air-exchange equipment (ventilation system, exhaust hoods, etc.) should be used to minimize the exposure of all persons to potentially toxic vapors. The concentration of glutaraldehyde, if it is used, in the air should never exceed allowable limites. There should be adequate space for drying and storage of endoscopes and endoscopic accessories.
20. Personal protective equipment (gloves, eyewear, respiratory protective devices, etc) should be readily available and should used to protect workers from exposure to infectious agents (HIV, hepatitis B virus, M tuberculosis, etc) and toxic chemicals.
21. All endoscopy personnel must be educated about the biologic and chemical hazards present while performing or assisting at endoscopic procedures and during the reprocessing of endoscopic equipment.
22. Endoscopy personnel should be trained according to the Occupational Safety and Health Administration's hazard communications standard. A spill containment plan specific for the liquid chemical sterilant/disinfectant being used should be available whenever and wherever endoscope reprocessing occurs.
23. Personnel should be vaccinated against preventable diseased such as hepatitis B. Those at risk for exposure to tuberculosis should be screened for infection by Mantoux skin testing with purified protein derivative.
24. Routine testing of liquid sterilants/high-level disinfectants should be performed to ensure minimal effective concentration of the active ingredient.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduced infectious complications of endoscopy and improved quality of patient care.
- Improved sterilization and disinfection procedures currently used in flexible endoscopy.

POTENTIAL HARMS

- Glutaraldehyde is irritating to the skin, can cause allergic contact dermatitis, and may cause irritation of the eyes and nasal mucosa. Dermatitis, eye irritation, throat discomfort, nasal irritation, and cough were reported in one study while in another rashes on the hands, eczema, nasal and throat irritation, as well as nausea and headache were acknowledged as the result of exposure to glutaraldehyde.
- Peracetic acid can cause severe burns as a result of direct contact, irreversible damage or blindness as a result of direct contact with the eyes, and inhalation results in irritation of the nose, throat and lungs.
- Phenolics can cause tissue irritation and injury to mucous membranes.

QUALIFYING STATEMENTS

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Re-use of single-use endoscopy devices/accessories. Recent attention has been focused on the possibility that "single-use" devices could be reprocessed and reused both safely and cost effectively. Such savings can be considerable, but studies to date have included only a few such devices. As a result, this approach remains controversial, and implementation of such a strategy requires a major institutional commitment, including a monitoring committee with clearly defined protocols. Manufacturers need to improve the design of endoscope accessories to ensure the ability to be safely and effectively cleaned and sterilized.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for Professionals in Infection Control and Epidemiology, Inc. APIC guideline for infection prevention and control in flexible endoscopy. Am J Infect Control 2000;28:138-55. [96 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000

GUIDELINE DEVELOPER(S)

Association for Professionals in Infection Control and Epidemiology, Inc. - Professional Association

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Association for Professionals in Infection Control and Epidemiology (APIC) Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Carla J. Alvarado and Mark Reichelderfer

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline replaces the original guideline published in 1994, "APIC guidelines for infection prevention and control in flexible endoscopy" (Am J Infect Control. 1994 Feb;22(1):19-38).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Association for Professionals in Infection Control and Epidemiology, Inc. Web site.

Print copies: Available for purchase from the Association for Professionals in Infection Control and Epidemiology, Inc., 1275 K Street, NW, Suite 1000, Washington, DC 20005-4006. For more information, please see the Association for Professionals in Infection Control and Epidemiology, Inc. Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 2, 2000. The guideline developer was provided with a copy of this NGC summary for review, but to date, NGC has not received any comments from the guideline developer.

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